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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,837	03/30/2004	David G. Malone	92030/03-701	3121
22206	7590	02/24/2006	EXAMINER	
			STEWART, ALVIN J	
			ART UNIT	PAPER NUMBER
			3738	
			DATE MAILED:	02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SPP

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/812,837	MALONE, DAVID G.
	Examiner Alvin J. Stewart	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 January 2006.  
 2a) This action is FINAL. 2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,2,4,11-16,18-21,23,24,35,36,38-40 and 47-55 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,2,4,11-16,18-20,23,24,35,36,38-40 and 47-55 is/are rejected.  
 7) Claim(s) 21 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 30 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 8/24/9/20/4;10/6/05

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

02/13/06

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Species IV in the reply filed on 01/30/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3, 5-10, 17, 22, 25-34, 37, and 41-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/30/06.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 11-16, 18, 23, 24, 35, 38-40, 47-49, 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonnell US Patent 6,126,688.

McDonnell discloses an interbody spine fusion (10) comprising a body (18) defining an outside surface, a carrier receiving area (14), an un-doped carrier material (12), a port (16) and a pathway (see side opening in Fig. 1).

Regarding claim 11, the ports 16 make the body a body-to-body appliance.

Regarding claim 12, the elements 20 make the body a bone-to-device appliance.

Regarding the biologically active substances (see col. 4, lines 43-49).

Regarding claims 15 and 16, see col. 4, lines 43-49).

Claims 1, 2, 18, 19, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Weber et al US Patent 6,482,234.

Weber et al discloses a spinal disc (20) comprising a body (24), a carrier receiving area (22), an un-doped carrier material (76), a port (aperture used to insert element 72), a pathway (slit used to insert syringe, see Fig. 7B) and a plug (72).

Claims 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Camino et al US Patent 6, 776,798 B2.

Camino et al discloses an interbody spine fusion (12) comprising a body (42) defining an outside surface, a carrier receiving area (32), an un-doped carrier material (see col. 4, lines 28-32), a port (see opening at the distal end of element 12), a pathway (44) and an end cap (10).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50-52 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonnell US Patent 6,126,688.

McDonnell discloses the invention substantially as claimed. However, McDonnell does not disclose the biologically active dissolvable, crystalline, a gel material and the migration of the biologically active substance is promoted by body heat.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the composition of the biologically active substance because Applicant has not disclosed that the difference in the composition provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with McDonnell composition because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify the McDonnell reference to obtain the invention as specified in claims 50-52 and 55.

*Allowable Subject Matter*

Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 6, 2006.

*A. Stewart*  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**